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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,353	11/27/2000	Yen Choo	PM273884	8682

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/14/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,353

Applicant(s)

CHOO ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-22,24 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,23,25,26,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

Response to Arguments

Applicants argue that they do not understand the term "feature step" as applied to claim 19. In response the additional feature step of claim 19 is step a). Neither claim 3 nor claim 4 recites the use of a model zinc finger domain. Thus, the step of selecting a natural or consensus zinc finger is not a limitation of claims 3 and 4. For the reasons set forth in the last Office action, Choo is a prior art. Furthermore, the consideration of the additional step is not only with respect to the presence of prior art. Rather, other patentability issues applicable to the additional process step(s).

Status of Claims

Claims 1-29 are pending.

Claims 1-2, 5-22, 24 and 27 are withdrawn from further consideration as being drawn to a nonelected invention and species.

Claims 3-4, 23, 25-26 and 28-29 are under examination.

Specification

In view of the newly submitted abstract, the objection with respect to the abstract no longer applies.

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The disclosure is objected to because of the following informalities: there is no SEQ.ID. No. assign for sequence A at page 7, lines 5 and 12 of the newly amended specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4, 23, 25-26 and 28-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification fails to provide an adequate description of the claimed "method for binding a DNA binding polypeptide to a DNA triplet in a target DNA sequence" and "exposing the DNA binding polypeptide to the target DNA" in the context of the claim. The as-filed specification describes a description of the method of making and method for determining

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the presence of a target modified nucleic acid. It does not describe a method for binding DNA binding polypeptide to its target. This preamble does not fall within the statutory subject matter of method of making or using. Applicants state that support for the newly presented claim "exposing" is found at page 26, lines 20-21. A review of the instant specification reveals said step in a method for determining the presence of a target modified nucleic acid molecule. Not for a method for binding a DNA binding polypeptide to a target DNA.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35

U.S.C. 112: .

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 23, 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons as they appear in the last Office action.

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Response to Arguments

A). Applicants argue that the amendment to claims 3 and 4 obviate this rejection. However, the newly amended claim 3 made the claim more confusing. The preamble recites "a method for binding a DNA binding polypeptide to Cys2 His2 zinc finger class to a DNA triplet". The body of the claim recites for preparing and then exposing without reciting a positive process steps. A method of binding is neither a method of making or using as required by the statute. Thus, the rejection as to the omission of the steps of making a DNA as stated in the last action makes the claim indefinite. It does not recite the steps by which a process of making is accomplished.

Applicants again request for clarification as to the conditional requirements recited in claim 4. The conditional requirement does not relate to the argued and deleted "capable of binding". Rather, to the numerous and different conditional "ifs".

Applicants argue that the negative limitation "is not Asp" may be broad but not indefinite as includes any other amino acid. In response, the negative limitation is not broad but indefinite for failing to circumscribe or distinctly point out the metes and bounds of said any amino acid except Asp.

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The rejection with respect to the terms "may be"; "and/or" "small" no longer applies with the amendment to the claim.

B. Withdrawn in view of the amendment to the claim.

C. Applicants argue that randomization and selection are additional limitations, which distinguish claim 26 from the base claim. A dependent claim incorporates every feature of the claim from which it depends. Thus, the process steps of randomization and screening do not add further limitation to the base claim. Rather, broadens the base claim. These additional steps require steps not present in the base claim. Claim 26 has been amended to substitute the term screening for selection. In response, the base claim 3 does not recite a randomization step. The limitation in claim 26 of further subjecting the DNA binding protein to one or more rounds of randomization and selection in order to improve the characteristics thereof is indefinite. Neither claim 3 or 4 contains any process steps of randomization and selection.

The newly amended claims are rejected under this statute as follows:

1. There appears to be a lack of nexus between the two method steps of preparing and exposing for binding effect, especially since all polypeptides binds to DNA one way or

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another. It is not clear as to the step included in the "whereby" clause of claim 3.

2. Claim 26 process of "screening" is indefinite as the base claim recites only a binding between DNA binding polypeptide to its target. It does not clearly state in what stage of the randomization screening is done for improve binding characteristics. The terms "improve" and "regulates" in claims 26 and 29 respectively are relative terms, which render the claim indefinite. The terms "improve" and "regulates" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

3. Claim 28 is unclear as to the step of detecting i.e., how detection or which binding is being detected. It is suggested that applicants recite for the detecting step. This step should be incorporated to the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

Claims 3, 4, 23, 25-26 and 28-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Choo (Comment, XP-002116419) for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that Choo is not prior art since they are entitled to their priority date of March 31, 1998. The priority date does not disclose a method of binding, as presently claimed. Furthermore, as stated in the last Office action, it appears that Choo made the method only by himself since the article repeatedly uses the pronoun "I".

Claims 3, 4, 23, 25-26 are rejected under 35 U.S.C. 102(d) as being anticipated by Choo (United Kingdom 9805576.7).

Response to Arguments

Applicants argue that the application was not filed more than 12 months before the effective U.S. filing date i.e., PCT filing of 3/17/99. It is further argued that the GB application

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has been abandoned and even to the present date has not matured into a granted patent. Also, that the cited GB application is a priority application of the present application.

In reply, the GB application does not have to mature into a patent to be a prior art. 35 USC 102(d) stature as provided by applicants present in the alternative that the application is the subject matter of an inventor's certificate. Furthermore, the GB application has a different inventive entity i.e., Choo, as the sole inventor, as opposed to the instant application having Isalan as a co-inventor.

Double Patenting

In view of the amendments to claim 4 the provisional rejection no longer applies.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

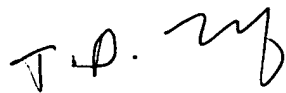
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

7/11/03